CDER Executive Staff Briefing
Electronic Submission Update

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Electronic submissions Update

- **Electronic Submission of NDAs - update**
- **Electronic Labeling**
- **Drug Registration and Listing**
- **Adverse Event Reports**
- **Clinical Trials Data Bank**
- **Promotional Material**
- **Other Electronic Submissions**
- **Secure Email**
- **Electronically signed CDER Letters**

Electronic submission of NDAs

Since February 1999 -

- Archival copy of NDA in electronic format
- Portion of the review copy in paper

Electronic submission of NDAs

- 45% of all applications submitted with an electronic component
- 80% of have either electronic CRFs and/or CRTs
- 15% are complete submission

Electronic submission of NDAs

Reduction in the average number of paper volumes from 1997
1998 - 20% reduction
1999 - 30% reduction
2000 - 50% reduction

Electronic submission of NDAs

Follow guidance

- ***Providing Regulatory Submissions in Electronic Format - NDA***

- ***Providing Regulatory Submissions in Electronic Format - General Considerations***

Electronic submission of NDAs

MaPP 7600.6 - *Requesting and Accepting Non Archival Records in Electronic Format for NDAs*

- **Archival file formats**
  - **Documents in PDF**
  - **Datasets in SAS transport file format**
- **No review aids**
  - **Except draft labeling in Word**

Electronic Submission - Labeling Text

Labeling text

- Content of package insert
- Includes all text, tables, and figures
- Print area 8.5 by 11
- 12 point font
- no columns

Electronic Submission - Labeling Text

- **Labeling submission - Improve the efficiency of review of labeling changes**
  - **Labeling history - all changes since the last approved labeling text**
  - **Last approved labeling text**
  - **Currently used labeling text**
  - **Proposed labeling text**

Electronic Submission - Labeling Text

Electronic labeling compare using Acrobat 4.0

- More efficient review of labeling changes
- Consider regulatory change to require labeling in electronic format

Electronic Submission of Drug Registration and Listing

Considering web based registration and listing

- More efficient processing
- Up to date drug listing information
- Complete drug listing database
- Improved public access to drug listing information

Other areas being considered for improving the dissemination of drug information

- Requiring NDC number on labeling
- Requiring bar coding of NDC, lot number, expiration number
- Internet based labeling repository
- User friendly internet based searching

Electronic Submission of Postmarketing Safety Reports

- **Pilot program for expedited reports**
- **Physical media, electronic transmission**
- **aerspilot@cder.fda.gov**

Clinical Trials Data Bank

- **FDAMA 113 project with NIH/NLM**
- **Internet based listing of information for ongoing clinical trials**
  - **Clinical trial details**
  - **Investigator information**
  - **Contact information**
- **Web based interface for entering information**

Electronic Promotional Material

- **PDF format**
  - **Launch material**
  - **Promotional material**
- **Draft guidance coming soon**
- **Pilot program coming soon**

Other Electronic Submissions

- **INDs**
- **Annual reports**
- **ANDAs**
- **DMF**

Secure Email

- **Exchange security keys between company and CDER**
- **No official submissions through email**
- **Contact Greg Brolund for details**
  brolund@cder.fda.gov

Division File System

- **Archive CDER generated documents concerning INDs and NDAs in PDF format**
- **Improved retrieval**
- **Improved access through FOI**
- **Electronic signatures on letters**
- **In effect as early as October 2000**

Need Help?

- **Electronic submission web page**
  www.fda.gov/cder/regulatory/ersr/default.htm

- **Electronic submission help**
  Esub@cder.fda.gov

- **Whatever**
  levinr@cder.fda.gov